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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,860	08/03/2001	Daniel E. Alesi	0100/0129	6633

21395 7590 03/16/2004

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,860

Applicant(s)

ALESI ET AL.

Examiner

Kathryn L Thompson

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4, 13 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 14-20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

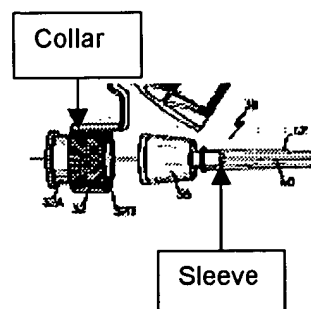
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8, 10, 12, 14, 15, 17, 18, 20, 22, 23, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Landis (US 5,490,841). Landis discloses an apparatus (Figure 4) comprising a holder having one and other ends, said one end having an extension (36) and a sleeve extending from said extension, a double ended needle (Column 7, Lines 29-44), a collar, a housing pivotally extending from said collar (12), and a sheath (42).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landis in view of Imbert (US 6,027,482). Landis teaches all of the claimed limitations except a tamper evident seal on said sheath and sleeve. Imbert discloses a tamper evident seal on said sheath and sleeve (Figure 8, #86). Imbert teaches that the tamper evident seal provides evidence as to whether or not the medical device has been tampered or misused (Column 6, Lines 51-58). It would have been obvious to one with ordinary skill in the art to use the teachings of Imbert to modify the invention of Hollister in order to create a safe tamper-free medical device.

Claims 1-3, 5-8, 10-12, 14, 15, 17-20, 22, 23, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (US 5,277,311) in view of Landis (US 5,490,841). Hollister discloses an apparatus comprising a holder (2) having an extension and a sleeve integrally extending from said extension, a double ended needle (28), a collar (18) rotatable about said extension, a housing (20) comprising an integral locking means, and a cover (Figure 1). Hollister discloses all of the claimed limitations except a sheath having an open end having a circumference that enables the sheath to matingly fit to said sleeve. Landis does disclose a sheath/cap/needle cover (42) having an open end. It would have been obvious to one with ordinary skill in the art to use the teachings of Landis to modify the invention of Hollister and put a sheath/cap/needle

cover on the needle in order to keep the needle sterile and prevent it from exposure to contaminants.

Claims 9, 16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister in view of Landis, further in view of Imbert (US 6,027,482). Hollister and Landis teach all of the claimed limitations except a tamper evident seal on said sheath and sleeve. Imbert discloses a tamper evident seal on said sheath and sleeve (Figure 8, #86). Imbert teaches that the tamper evident seal provides evidence as to whether or not the medical device has been tampered or misused (Column 6, Lines 51-58). It would have been obvious to one with ordinary skill in the art to use the teachings of Imbert to modify the invention of Hollister and Landis in order to create a safe tamper-free medical device.

Response to Arguments

In view of the Appeal Brief filed on September 22, 2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Art Unit: 3763

Applicant's arguments with respect to claims 1-3, 5-12, 14-20, 22-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT

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BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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